IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA

BOEHRINGER INGELHEIM PHARMA GMBH & CO. KG, BOEHRINGER INGELHEIM INTERNATIONAL GMBH, and BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.,

Plaintiffs,

v.

MYLAN PHARMACEUTICALS INC.,

Defendant.

C. A. No. 1:14-CV-146

COMPLAINT

Plaintiffs Boehringer Ingelheim Pharma GmbH & Co. KG, Boehringer Ingelheim International GmbH, and Boehringer Ingelheim Pharmaceuticals, Inc. (together, "Boehringer" or "Plaintiffs"), by their undersigned attorneys, for their Complaint against Defendant Mylan Pharmaceuticals Inc. ("Mylan"), hereby allege as follows:

THE PARTIES

1. Plaintiff Boehringer Ingelheim Pharma GmbH & Co. KG ("BIPKG") is a limited partnership organized and existing under the laws of Germany, having a principal place of business at Binger Strasse 173, 55216 Ingelheim, Germany.

2. Plaintiff Boehringer Ingelheim International GmbH ("BII") is a private limited liability company organized and existing under the laws of Germany, having a principal place of business at Binger Strasse 173, 55216 Ingelheim, Germany.

3. Plaintiff Boehringer Ingelheim Pharmaceuticals, Inc. ("BIPI") is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 900 Ridgebury Road, Ridgefield, Connecticut 06877.

4. Upon information and belief, Mylan is a corporation organized and existing under the laws of West Virginia, having a place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505.

NATURE OF THE ACTION

5. This is a civil action concerning United States Patent No. 6,015,577 ("the '577 patent"). This action arises under the Patent Laws of the United States, 35 U.S.C. § 100, *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02.

JURISDICTION AND VENUE

6. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

7. Venue is proper in this Court under 28 U.S.C. §§ 1391(c) and 1400(b).

8. Upon information and belief, Mylan develops, manufactures, and/or distributes generic drugs for sale and use throughout the United States, including in this Judicial District.

9. This Court has personal jurisdiction over Mylan by virtue of, *inter alia*, its incorporation under the laws of the State of West Virginia, and because it maintains its principal place of business in the State of West Virginia.

BACKGROUND

10. BIPI is the holder of New Drug Application ("NDA") No. 20-884, by which the United States Food and Drug Administration ("FDA") first granted approval for 200 mg extended-release dipyridamole / 25 mg acetylsalicylic acid ("aspirin") capsules. The dipyridamole/aspirin capsules described in BIPI's NDA are prescribed to reduce the risk of stroke in patients who have had transient ischemia of the brain or completed ischemic stroke due

to thrombosis. Boehringer sells these capsules in the United States under the trade name "AGGRENOX®."

11. BIPKG owns the '577 patent, which was duly and legally issued on January 18, 2000, and is titled "Pharmaceutical Compositions Containing Dipyridamole or Mopidamol and Acetylsalicylic Acid or the Physiologically Acceptable Salts Thereof, Processes for Preparing Them and Their Use in Treating Clot Formation." BII has an exclusive license under the '577 patent in the United States from BIPKG. BIPI has an exclusive license under the '577 patent in the United States from BII. A copy of the '577 patent is attached as Exhibit A.

12. Mylan's Abbreviated New Drug Application ("ANDA") No. 206782 (the "Mylan ANDA") seeks approval to engage in the manufacture, use, sale, offer for sale, and/or importation of 200 mg extended-release dipyridamole / 25 mg aspirin capsules ("Mylan's ANDA product") prior to the expiration of the '577 patent.

13. Mylan sent a letter dated July 16, 2014 ("Notice Letter") to BIPI and BIPKG in which Mylan represented that it had filed an ANDA for Mylan's ANDA product, which allegedly includes a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV certification") of invalidity and/or noninfringement concerning the '577 patent. The Notice Letter indicates that Mylan seeks approval of the Mylan ANDA prior to the expiration of the '577 patent.

14. This action was commenced within 45 days of the receipt of Mylan's Notice Letter by BIPKG and BIPI.

15. Upon information and belief, Mylan was aware, before July 16, 2014, of the lawsuits *Boehringer Ingelheim Pharma GmbH & Co. KG, et al. v. Barr Laboratories*, Civil Action No. 07-cv-432 (GMS) (D. Del.) ("Boehringer/Barr"), and *Boehringer Ingelheim Pharma*

GmbH & Co. KG, et al. v. Kremers Urban Pharmaceuticals Inc., Civil Action No. 13-cv-1580 (NLH)(KMW) ("Boehringer/Kremers"), the latter of which was pending in the United States District Court for the District of New Jersey as of the date of the Notice Letter.

16. Upon information and belief, Mylan was aware, at some time before July 16, 2014, that a generic challenge to the '577 patent was possible under FDA regulations on or after January 31, 2000.

17. Mylan first raised a challenge to the '577 patent more than fourteen years after a challenge was first possible under FDA regulations, more than five years after the conclusion of the Boehringer/Barr litigation, and more than one year after the commencement of the Boehringer/Kremers litigation.

18. Upon information and belief, Mylan's ANDA product is a pharmaceutical composition containing 25 mg aspirin and 200 mg dipyridamole.

19. Upon information and belief, Mylan's ANDA product is a capsule containing 25 mg aspirin as a tablet and 200 mg dipyridamole as extended-release pellets.

20. Upon information and belief, the dipyridamole pellets in Mylan's ANDA product have a coating including lacqueurs which are insoluble in acid, but soluble in intestinal juices.

21. Upon information and belief, Mylan's ANDA product seeks approval for the following indication: "to reduce the risk of stroke in patients who have had transient ischemia of the brain or completed ischemic stroke due to thrombosis."

22. Upon information and belief, Mylan has applied for a use of Mylan's ANDA product that will inhibit the occurrence of strokes of the type caused by a blood clot when administered to a patient requiring inhibition of venous or arterial clot formation.

23. Mylan's Notice Letter does not deny infringement of claims 13-14 and 16-20 of the '577 patent separate and apart from a defense of patent invalidity.

24. The only patent invalidity defenses asserted in Mylan's Notice Letter are the defenses of obviousness under 35 U.S.C. § 103 and anticipation under 35 U.S.C. § 102.

25. Mylan's Notice Letter cites the disclosures in U.S. Patent No. 4,367,217 ("Gruber") and U.S. Patent No. 4,694,024 ("Weithmann"), both of which were of record in the United States Patent and Trademark Office ("PTO") during prosecution of the application for the '577 patent.

26. The PTO determined that the '577 patent claims were patentable notwithstanding the disclosures of Weithmann and Gruber.

27. No reference cited in Mylan's Notice Letter discloses a pharmaceutical composition for oral administration comprising:

> a first component selected from the group consisting of dipyridamole, and the pharmaceutically acceptable salts thereof; and
>
> a second component selected from the group consisting of acetylsalicylic acid and the pharmaceutically acceptable salts thereof;
>
> said first and second components being present in a weight ratio in the range between 8:1 and 100:1;
>
> a pharmaceutically acceptable acid excipient formulated together with said first component in the form of pellets provided with a coating made up of 50 to 100% of lacqueurs which are insoluble in acid but soluble in intestinal juices and 50 to 0% of lacqueurs which are insoluble in both gastric and intestinal juices, and said acid excipient being in a ratio of at least one equivalent of said acid excipient to 1 mol of said first component;
>
> said second component being present in the form of a tablet; and all components being contained together within a capsule.

28. No reference cited in Mylan's Notice Letter discloses a pharmaceutical composition for oral administration wherein dipyridamole is present in an amount between 75 and 400 mg and aspirin is present in an amount of 5 to 80 mg.

29. No reference cited in Mylan's Notice Letter discloses a pharmaceutical composition for oral administration comprising:

> a first component selected from dipyridamole and the pharmaceutically acceptable salts thereof; and
> a second component selected from acetylsalicylic acid and the pharmaceutically acceptable salts thereof; and,
> wherein the quantities of the first and second components are adjusted so that the weight ratio between them is between 8:1 and 100:1.

30. No reference cited in Mylan's Notice Letter discloses a pharmaceutical composition for oral administration comprising:

> dipyridamole; and,
> acetylsalicylic acid;
> wherein the quantities of dipyridamole and acetylsalicylic acid are adjusted so that the final dosage form comprises 200 mg of dipyridamole and 25 mg of acetylsalicylic acid, and so that the weight ratio between them is 8:1.

31. No reference cited in Mylan's Notice Letter discloses a method for inhibiting the formation of venous and arterial blood clots, which comprises administering to a patient requiring inhibition of venous or arterial clot formation a first drug selected from the group consisting of dipyridamole and the pharmaceutically acceptable salts thereof and a second drug selected from the group consisting of acetylsalicylic acid and the pharmaceutically acceptable salts thereof, with said first and second drugs being administered in a weight ratio in the range between 8:1 and 100:1.

32. No reference cited in Mylan's Notice Letter discloses a method for inhibiting the occurrence of temporary ischemic episodes, which consists of administering to a patient requiring inhibition of venous or arterial clot formation a first drug selected from the group consisting of dipyridamole and the pharmaceutically acceptable salts thereof and a second drug selected from the group consisting of acetylsalicylic acid and the pharmaceutically

acceptable salts thereof, with said first and second drugs being administered in a weight ratio in the range between 8:1 and 100:1.

33. No reference cited in Mylan's Notice Letter discloses a method for inhibiting the occurrence of strokes of the type caused by a blood clot, which consists of administering to a patient requiring inhibition of venous or arterial clot formation a first drug selected from the group consisting of dipyridamole and the pharmaceutically acceptable salts thereof and a second drug selected from the group consisting of acetylsalicylic acid and the pharmaceutically acceptable salts thereof, with said first and second drugs being administered in a weight ratio in the range between 8:1 and 100:1.

CLAIM FOR RELIEF

34. Plaintiffs reallege paragraphs 1-33 as if fully set forth herein.

35. Because Mylan seeks approval of the Mylan ANDA to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of a drug claimed in the '577 patent, and/or whose approved use is also claimed in the '577 patent, before its expiration, Mylan has infringed the '577 patent pursuant to 35 U.S.C. § 271(e)(2)(A).

36. Plaintiffs are entitled to a declaration that, if Mylan commercially manufactures, uses, sells, offers to sell, and/or imports any of Mylan's ANDA product, or induces or contributes to any such conduct, it would further infringe the '577 patent pursuant to 35 U.S.C. § 271(a), (b), and/or (c).

37. Upon information and belief, the commercial manufacture, use, sale, offer to sell, and/or importation of Mylan's ANDA product, if approved by the FDA prior to the expiration of the '577 patent for use in accordance with its proposed labeling, would infringe and/or induce and/or contribute to the infringement of the '577 patent. Boehringer is entitled to relief provided by 35 U.S.C. § 271(e)(4), including an Order of this Court that the effective date

of the approval of Mylan's ANDA No. 206782 be a date that is not earlier than the expiration date of the '577 patent, or any later expiration of exclusivity for the '577 patent to which Boehringer is or may become entitled.

38. At least claims 13-14 and 16-20 of the '577 patent encompass within their scope Mylan's ANDA product. Mylan's ANDA product would therefore literally infringe at least those claims.

39. Upon information and belief, Mylan was aware of the existence of the '577 patent, and was aware that the filing of Mylan's ANDA and a Paragraph IV certification with respect to the '577 patent constituted an act of infringement of that patent.

40. Mylan's statements of the factual and legal bases for its opinion regarding the invalidity of the '577 patent are devoid of any objective good-faith basis in either the facts or the law.

STATEMENT REGARDING PRIOR-FILED SUIT

41. Boehringer previously filed, on July 30, 2014, an action seeking to enjoin Mylan from infringing the '577 patent in the District of New Jersey, and that action has been assigned Civil Action No. 1:14-cv-04727-NLH-KMW ("Boehringer-Mylan D.N.J. Action").

42. The Boehringer-Mylan D.N.J. Action involves the same patent and same Plaintiff as an action also currently pending in the District of New Jersey against Defendant Amneal Pharmaceuticals LLC, assigned Civil Action No. 1:14-cv-04726-NLH-KMW ("Boehringer-Amneal D.N.J. Action"), as well as a recently dismissed action in the District of New Jersey against Defendant Kremers Urban Pharmaceuticals Inc., assigned Civil Action No. 1:13-cv-01580-NLH-KMW ("Boehringer-Kremers D.N.J. Action"). The Boehringer-Mylan

D.N.J. Action was designated as related to the Boehringer-Amneal D.N.J. Action and the Boehringer-Kremers D.N.J. Action, and all three cases are assigned to Judge Noel L. Hillman.

43. In the Boehringer-Mylan D.N.J. Action, Boehringer alleged that the District Court for the District of New Jersey has personal jurisdiction over Mylan with regard to Boehringer's claim of patent infringement.

44. Judicial economy would be promoted, and Boehringer's choice of forum respected, if the claim related to Boehringer's action for infringement of the '577 patent is addressed by Judge Hillman in the District of New Jersey.

45. Mylan did not contest personal jurisdiction in New Jersey for the purpose of a Hatch-Waxman Act litigation in the matter of *Warner Chilcott Company, LLC v. Mylan Inc., Mylan Pharmaceuticals Inc., and Family Care Ltd*, No. 3:13-cv-06560-JAP-TGB, D.I. 19 at 4 (D.N.J. May 20, 2014) .

46. Before the filing of the present action, Mylan was asked to consent to personal jurisdiction in New Jersey for the purpose of the Boehringer-Mylan D.N.J. Action, but has not responded.

47. Pursuant to 21 U.S.C. § 355(j)(5)(B)(iii), a patent owner has 45 days from receipt of an ANDA Notice Letter to file suit in order to perfect its statutory right to a stay of FDA approval of an ANDA pending resolution of litigation regarding the submission of such ANDA. Boehringer filed this action as a further protective measure with regard to this statutory right in light of Mylan's silence regarding whether it will contest personal jurisdiction in New Jersey in the Boehringer-Mylan D.N.J. Action. Boehringer expects that personal jurisdiction will be maintained in the District of New Jersey and that the action will proceed in that forum. In that circumstance, this action would be unnecessary and may be voluntarily dismissed without

prejudice in favor of continued prosecution of the Boehringer-Mylan D.N.J. Action, transferred to the District of New Jersey for consolidation with the Boehringer-Mylan D.N.J. Action, or subject to such other non-substantive disposition that would ensure maintenance of Boehringer's rights pursuant to 21 U.S.C. § 355(j)(5)(B)(iii).

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. A Judgment be entered that Mylan has infringed the '577 patent by submitting ANDA No. 206782;

B. A Judgment be entered that this case is exceptional, and that Plaintiffs are entitled to their reasonable attorney fees pursuant to 35 U.S.C. § 285;

C. A permanent injunction be issued, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining Mylan, its officers, agents, attorneys, and employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of the drugs or methods of administering drugs claimed in the '577 patent prior to its expiration, including any exclusivities or extensions.

D. An Order be issued pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of any approval of Mylan's ANDA No. 206782 be a date that is not earlier than the expiration date of the '577 patent, or any later expiration of exclusivity for the '577 patent to which Plaintiffs are or may become entitled; and

E. Such other and further relief as the Court may deem just and proper.

Dated: August 29, 2014

Respectfully submitted,

By: /s/ James F. Companion

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